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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/830,795 | 04/30/2001 | Marten Stjernstrom | P0214 | 3545 |
| 26271 | 7590 | 10/27/2003 | EXAMINER | |
| FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095 | | | HANDY, DWAYNE K | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1743 | | |

DATE MAILED: 10/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/830,795 | STJERNSTROM, MARTEN |
| | Examiner Dwayne K Handy | Art Unit 1743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) 4 and 5 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1 and 3</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 4 and 5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claims 4 and 5, applicant appears to be attempting to place limitations on the microvolume of fluid which is manipulated in the device. The fluid is not part of the device, however, so this limitation does not further limit the device.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 4-8, 10, 12 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Litborn et al. (WO 98/33052). Litborn teaches a method of preventing evaporation from liquid samples in small volumes. The method includes providing a plate with wells for depositing a sample upon (the plate is best shown in Figure 1),

depositing sample material into a well (called a vial in the reference) on a flat surface, allowing solvent containing the sample to evaporate, replacing the evaporated solvent with fresh solvent. This is shown in Figures 2A, 3A and 4. Figure 4 shows the deposition of a sample. Figures 2A and 3A show the continuous addition of solvent (or "covering liquid") to the sample. The process is also described in Example 1 on page 16, lines 13-34 in reference to Figure 8. This section also includes the use of flow controlled micropumps attached to narrow bore capillaries for the addition of fluid to the wells. The Examiner considers this capillary for delivering the solvent as meeting the limitations of the reservoir and microchannel of the instant device. The open microarea would be the wells.

4. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Mian et al. (6,319,469). Mian teaches a circular platform with wells, channels and reservoirs for analyzing microvolumes of liquid. The embodiment most relevant to the instant claims is shown in Figures 13A-13C and described in column 26. In Figures 13A-13C, Mian shows a sample loader which may be used to load the circular disc with the microfluidic elements. The loader may be used to load a wide variety of fluids (col. 26, lines 34-48) into input ports. The ports are shown in a circular array in Figure 13C. The loading device is comprised of barrels containing the liquids to be inserted as well as hollow tubes (col. 26, l. 24-25) that may be used manipulate fluids in conjunction with positive or negative pressure. The Examiner considers the pipette barrels and hollow tube for

inputting samples as meeting the limitations of the reservoir and microchannel of the instant device. The open microarea would be the input port.

5. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Kennedy (6,488,895). Kennedy teaches a multiplexed microfluidic device and system comprised of a plurality of ports, reservoirs and microchannels. The embodiment of Kennedy's device most relevant to the instant claims is shown in Figure 3 and is described in column 8, line 50 – column 9, line 28. The device contains a number of ports (226A, 228A, 230A, 232A) that may be used to fill reservoirs (226, 228, 230, 232) that are situated below them. The reservoirs are also connected by a microchannel network (224) that would allow for the transfer of material from any of the reservoirs to another. The Examiner considers the open ports used for inputting samples as meeting the limitations of the open microarea. Any ports which are not used for input would then be a reservoir which could be used to load the port area since there is no limitation on how the open microarea is loaded.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Litborn et al. (WO 98/33052) in view of Mian et al. (6,319,469). Litborn, as described above in paragraph 3, teaches every element of claims 9 and 11 except for the microarea, microchannel, and reservoir being part of a microfluidic device and the step of anchoring the sample in the microarea. Mian teaches a microfluidic device used to analyze microsamples. The device is comprised of a microchannel network that is loaded through an array of input ports by a sample loader (column 26). The sample loader may be used in a dynamic manner (col. 26, lines 49-51), but the use of solvent is not mentioned. Mian teaches anchoring material in the device in column 38, lines 8-33. It would have been obvious to combine the teachings of Mian with the method of Litborn. One would add the teachings of Mian in order to use the analytical elements of their device. One would anchor the material in the channels or reservoirs in order identify sample material through the use of specific binding partners as taught by Mian.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Demers (5,879,632 and 6,033,544) and Zanzucchi et al. (5,846,396) also teach liquid distribution systems which transfer microvolumes of liquids between chambers in microfluidic devices. Sundberg et al. (6,451,188) teaches a microfluidic structure for introducing fluids into a port. Sheppard, Jr. et al. (6,143,247) and Kellogg et al. (6,143,248) teaches circular array microfluidic devices which analyze microvolumes of fluid. Southgate et al. (5,863,801) teach a microfluidic device for analyzing nucleic acid samples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

Dkh
September 28, 2003